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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/615,884	07/08/2003	Morteza Gharib	06618-915001	9837
. 20985 FISH & RICH.	7590 06/20/200° ARDSON PC	EXAMINER		
P.O. BOX 102	2	HOLMES, REX R		
MINNEAPOLIS, MN 55440-1022			ART UNIT	PAPER NUMBER
			3762	
			MAIL DATE	DELIVERY MODE
			06/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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	Application No.	Applicant(s)			
Office Action Occurrence	10/615,884	GHARIB, MORTEZA			
Office Action Summary	Examiner	Art Unit			
	Rex Holmes	3762			
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address			
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION  (6(a). In no event, however, may a reply be tim  ill apply and will expire SIX (6) MONTHS from  cause the application to become ABANDONEI	l. ely filed the mailing date of this communication. D (35 U.S.C. § 133).			
Status					
1)⊠ Responsive to communication(s) filed on 10 Ag	oril 2007				
	action is non-final.				
·					
	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.				
Disposition of Claims					
4)⊠ Claim(s) <u>10-23</u> is/are pending in the application	1				
, , , , , , , , , , , , , , , , , , , ,	4a) Of the above claim(s) is/are withdrawn from consideration.				
5) Claim(s) is/are allowed.					
6)⊠ Claim(s) <u>10-23</u> is/are rejected.					
7) Claim(s) is/are objected to.					
8) Claim(s) are subject to restriction and/or	election requirement				
, , , , , , , , , , , , , , , , , , ,	ciccion requirement.				
Application Papers					
9) The specification is objected to by the Examiner					
10)☐ The drawing(s) filed on is/are: a)☐ acce					
Applicant may not request that any objection to the c					
Replacement drawing sheet(s) including the correcti	· · · · · · · · · · · · · · · · · · ·	• •			
11) The oath or declaration is objected to by the Ex	aminer. Note the attached Office	Action or form PTO-152.			
Priority under 35 U.S.C. § 119	,				
12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of:		-(d) or (f).			
1. Certified copies of the priority documents have been received.					
2. Certified copies of the priority documents have been received in Application No					
3. Copies of the certified copies of the priority documents have been received in this National Stage					
application from the International Bureau (PCT Rule 17.2(a)).					
* See the attached detailed Office action for a list of the certified copies not received.					
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Attachment(s)		,			
Notice of References Cited (PTO-892)	4) Interview Summary Paper No(s)/Mail Da				
2) Information Disclosure Statement(s) (PTO/SB/08)	5) 🔲 Notice of Informal P				
Paper No(s)/Mail Date	6)				

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#### **DETAILED ACTION**

### Response to Arguments

- 1. Applicant's arguments filed 4/10/07 have been fully considered but they are not persuasive.
- 2. The Applicant argues that Seitz and/or Seitz in view of Gharib do not measure the formation number over time and make a comparison between the measured formation number and a baseline formation number. In response Seitz shows that they quantify the degree of valvular stenosis by using the calculated value for valve function. If Seitz did not utilize a baseline number then the calculated value would be useless as it would just be a number without any meaning. Alternatively, Seitz discloses the method of obtaining the formation number and quantifying the degree of valvular stenosis, and Gharib further teaches a baseline comparison in the figure graphing the results for DCM patients versus normal patients using a formation number would encompass the claimed comparison to a baseline (Pages, 34-35). The figure shows a formation number, a baseline and a space between that is the differential formation number. The figure further shows the change in difference between the formation number and the baseline over different age periods. Seitz in view of Gharib teach the claimed invention.
- 3. The Applicant further argues that Seitz uses a series of assumptions to determine the valve function. This argument is moot as the claims do not limit the formation to a number that does not contain any assumed values.
- 4. The rejection is amended to include rejections to newly added claims 22 and 23.

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## Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

# Claim Rejections - 35 USC § 103

- 6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 7. Claims 10-11, 13, 16-19 and 22-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Seitz et al. (U.S. Pat. 6,149,595 hereinafter "Seitz") or, in the alternative, under 35 U.S.C. 103(a) as obvious over Seitz in view of Gharib et al., the 1994 article submitted by the applicant (hereinafter "Gharib").
- 8. Seitz discloses a non-invasive method utilizing ultrasound scanning to determine cardiac valve function (Col. 41, Table 16). Seitz discloses a method that utilizes time, velocity and valve area to determine valve function which is considered the claimed formation number (Cols. 52). Seitz also discloses that it utilizes existing values determined through traditional methods as a baseline comparison for valve function (Col. 2, II. 1-12), this comparison is a differential value that constitutes a dimensionless value.

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In the alternative, Seitz discloses the method of determining cardiac valve function as disclosed above, but Seitz does not call the combination of time, velocity, and valve area a formation number. However, Gharib discloses a formation number created from time, velocity, and valve area to determine the flow process in the left ventricle and the efficiency of the valves (Pages, 34-35). Gharib further teaches a baseline comparison in the figure graphing the results for DCM patients versus normal patients using a formation number would encompass the claimed comparison to a baseline (Pages, 34-35). This comparison between the baseline and the formation number is a pure number and constitutes a dimensionless number. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method as taught by Seitz, with the formation number as taught by Gharib since it was known in the art that the combination of time, velocity and valve area is used to determine valve function.

9. Claims 12, 14-15 and 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seitz or Seitz in view of Gharib as applied above. Although Seitz or Seitz in view of Gharib do not specifically disclose that it determines atrial fibrillation, it would have been obvious to use the Seitz or Seitz in view of Gharib method to determine atrial fibrillation as the dysfunction indicated as Atrial fibrillation is a common arrhythmia that accompanies mitral incompetence. As to the type of imaging used for blood flow studies, merely changing to another known imaging method at the time of the invention, would have been obvious as it is well known in the art that different imaging methods produce interchangeable results.

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#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rex Holmes whose telephone number is 571-272-8827. The examiner can normally be reached on M-F 8:00 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Réx Holmes Examiner Art Unit 3762 George Evanisko Primary Examiner Art Unit 3762

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